Washington State Medical Test Site Certificate of Waiver requirements, and SARS-CoV-2 (COVID-19) testing and test result reporting guidance document

This document is intended to help facilities in Washington understand the regulatory requirements for performing testing authorized for use under a certificate of waiver and provide guidance for maintaining compliance with the state Washington State Medical Test Site SARS-CoV-2 (COVID-19) test result reporting rules.

On August 26, 2020, the Centers for Medicare and Medicaid Services (CMS) issued a memorandum (PDF) regarding new reporting requirements for laboratories performing SARS-COV-2 (COVID-19) testing. These new reporting requirements were posted to the federal register on September 2, 2020. Changes to federal Clinical Laboratory Improvement Amendments (CLIA) rules are to include new requirements for on-site reviews of certificate of waiver and provider performed microscopy licenses to verify compliance with the new and existing rules. Additionally, on January 8, 2021 CMS issued QSO memo 21-10-CLIA regarding the requirements for reporting SARS-CoV-2 test results.

Washington is an exempt state from CMS federal enforcement and oversight under CLIA. In order to maintain this exemption, the Washington State Medical Test Site Program (MTS) must ensure the following:

- Have state laws in effect that provide for a state licensure program that has requirements that are equal to or more stringent than CLIA condition-level requirements for laboratories.
- Have implemented a state licensure program with requirements that are equal to or more stringent than the CLIA condition-level requirements such that a laboratory licensed by the state program would meet the CLIA condition-level requirements if it were inspected against those requirements.
- Have a state licensure program that meets or exceed the requirements of §§ 493.553, 493.555, and 493.557(b) and are suitable for approval by us under § 493.551(a).

In response to the changes to federal CLIA requirements, the Washington State MTS Program has developed and implemented a new medical test site emergency rule under Notification Requirements WAC 246-338-026(7) to maintain equivalent enforcement and oversight of SARS-COV-2 (COVID-19) test result reporting. Additionally, policy and procedure updates were made to include for performing on-site reviews for SARS-COV-2 (COVID-19) test result reporting, imposition of civil money penalties (CMP), and reporting condition level non-compliance to CMS.

New WAC emergency rule under WAC 246-338-026(7)

During the public health emergency, as defined in 42 C.F.R. 400.200, each medical test site that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 must report SARS-CoV-2 test results to HHS in such form and manner, and at such timing and frequency, as the department may prescribe. For the purposes of this subsection, "SARS-CoV-2 test" means any test that is intended to detect SARS-CoV-2 or diagnose a possible case of COVID-19.

- This applies to all medical test site certificate types. A medical test site must have documentation that it has reported all SARS-CoV-2 test results. Evidence of compliance with this standard includes that the medical test site attempted to report all of the SARS-CoV-2 test results but such results were not accepted due to factors outside of the laboratory's control — for example, if local or state health departments are not accepting negative results or are not equipped for the volume of reporting required.

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The Medical Test Site Revised Code of Washington (RCW) 70.42 and Washington Administrative Code Chapter 246-338, govern clinical testing performed in Washington state. In this section the requirements for performing testing under a certificate of waiver are listed under WAC 246-338-020(1) in Table 020-1, which is provided below:

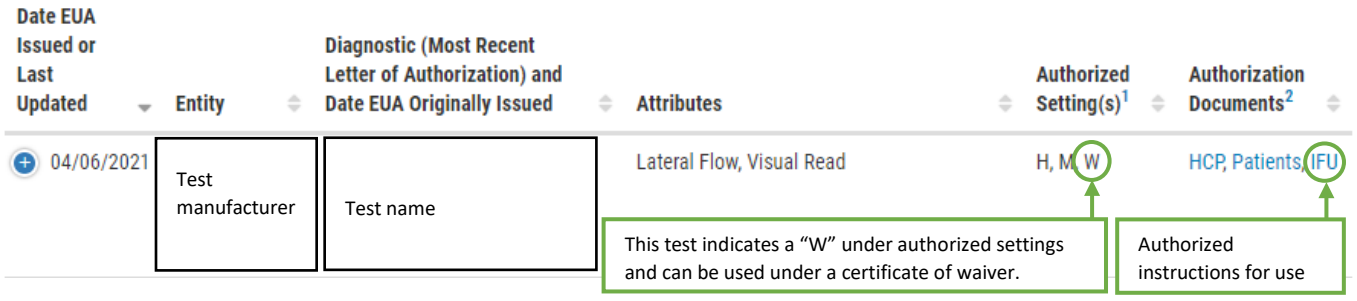
LICENSE TYPE	REQUIREMENTS	INSPECTIONS	
		TYPE	FREQUENCY
Certificate of Waiver*	• Restrict testing to tests classified as waived. • Follow manufacturers' instructions for performing the test. • Meet the requirements of WAC 246-338-020 Licensure—Types of Medical Test Site Licenses; WAC 246-338-022 Initial Application for Medical Test Site License; WAC 246-338-024 License Renewal/Reapplication Process; WAC 246-338-026 Notification Requirements; WAC 246-338-028 On-site Inspections.	• Complaint • Technical Assistance • As required to assess compliance with WAC 246-338-026(7)	•When indicated
• There are additional rule and inspection requirements for testing under Provider Performed Microscopy Procedures (PPMP), Categorized and Accredited licenses please review WAC 246-338-020 in Table 020-1.			

Breaking down the requirements for waived testing

Restrict testing to tests classified as waived

Under a certificate of waiver, a facility may perform tests that are classified as waived including those that have received an emergency use authorization (EUA) by the Food and Drug Administration (FDA) to be performed in patient care settings under a MTS/CLIA certificate of waiver.

SARS-COV-2 tests with EUAs are located on the FDA In Vitro Diagnostics webpage. Select the test methodology you are performing, molecular (PCR/NAAT), antigen, or serology listed under "Tables of IVD EUA." You can determine if your test is authorized for use in a waived setting by reviewing its listing on the FDA In Vitro Diagnostics webpage as demonstrated below:



Follow manufacturers' instructions for performing the test

The instructions for use (IFU) are developed by manufacturer of the test and are approved by the FDA. They are intended to provide the user of the test with clear, concise information easily understood for the safe and effective use of the test. Until such time as the FDA authorizes a revised IFU for an EUA, under the terms of the EUA, the laboratory must follow the currently authorized IFU.

MTS surveyors evaluate the laboratory's compliance with MTS rule requirements, including following manufacturer's instructions and verification/establishment of performance specifications. The manufacturer's instructions for all tests that have an EUA must be followed, to include quality control (QC).
How to interpret what is required by the manufacturer:

- Words such as "always," "will," "shall," "must," and "required" mean the instruction is mandatory and must be performed.
- Words such as "should" or "recommend" mean the action is not mandatory and is optional, but it is good laboratory practice to perform those actions.

Examples of IFU requirements approved by the FDA (this list is not extensive. Requirements will vary by the test system):

- Authorized laboratories using your product must include with test result reports, all authorized fact sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories using your product must use your product as outlined in the Instructions for Use. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
- Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product before initiating testing.
- Authorized laboratories using your product must have a process in place for reporting test results to health care providers and relevant public health authorities, as appropriate.
- Authorized laboratories will collect information on the performance of your product and report to the FDA and manufacturer any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
- All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.
- Authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

SARS-CoV-2 Molecular and Antigen Point of Care Test Enforcement Discretion:

- The Medical Test Site (MTS) program will temporarily exercise enforcement discretion for the duration of the COVID-19 public health emergency for the use of authorized SARS-CoV-2 molecular and antigen POC tests on asymptomatic people outside of the test's authorization. Specifically, MTS surveyors will not cite facilities with a MTS/CLIA certificate of waiver when authorized SARS-CoV-2 molecular or antigen POC tests are performed on asymptomatic people outside of the test's authorization, when done so considering the information in FDA's FAQ. In addition, MTS surveyors will not cite nonwaived facilities when modified, authorized, cleared or approved SARS-CoV-2 molecular or antigen POC tests are performed on asymptomatic people without establishing performance specifications for this population.

Quality Control (QC)/Performance Specifications:

- IFU QC requirements vary across test systems, especially when an emergency use authorization (EUA) is involved (e.g., should versus must), particularly for the serology antibody tests. For certain tests with EUAs the MTS requirements at WAC 246-338-090 apply based on language within the IFU. However, because IFU language varies, the medical test site will need to determine if the minimum QC requirements apply for each EUA test. **Surveyors will need to forward the specific EUA or provide a copy of, or link to, the IFU so that the MTS program can evaluate what QC requirements apply, should the surveyor have questions related to QC.**
- Facilities may also send a copy of their IFU to lqa@doh.wa.gov for review by the MTS program.

Specimen Type

- Specimen types listed in the intended use section of the IFU are acceptable for use with the assay under the EUA.
- To be covered by the EUA, specimens need to be collected according to the EUA's testing requirements and in accordance with the manufacturer's instructions and CDC guidelines.
- Any laboratory intending to modify a previously EUA-authorized COVID-19 assay, including the intended use (other than for testing asymptomatic people) or specimen type, must be CLIA-certified for high complexity testing, establish performance specifications, and be in compliance with the high complexity requirements.

Personnel requirements

- There are no education requirements (such as high school or bachelor's degree) for personnel performing testing authorized as waived by the FDA.
- Testing personnel must be trained according the EUA for the individual waived test.
- Individuals performing collections must meet the licensure requirements listed in the DOH providers authorized to collect nasal swab specimens for COVID-19 testing.

Meet the requirements of WAC 246-338-020 Licensure—Types of Medical Test Site Licenses

After July 1, 1990, any person advertising, operating, managing, owning, conducting, opening, or maintaining a medical test site must first obtain a license from the department. License types are described in Table 020-1 (provided on page 1).

Meet the requirements of WAC 246-338-022 Initial Application for Medical Test Site License

Applicants requesting a medical test site license must submit an accurate and complete certificate of waiver medical test site/CLIA application before beginning testing.

Meet the requirements of WAC 246-338-024 License Renewal/Reapplication Process

In Washington, all medical test site/CLIA licenses expire on June 30 of odd-numbered years. In April and May of the years leading up to the expiration of the license, the Department of Health will send out renewal cards notifying you of your upcoming license expiration. To continue performing testing your facility must renew its medical test site license every two years as required.

Meet the requirements of WAC 246-338-026 Notification Requirements

The owner must notify the department in writing at least 30 days before the opening or closing of a medical test site.

- To open a medical test site for certificate of waiver the owner must complete the certificate of waiver MTS/CLIA license application (PDF).
- To close a medical test site, send an email with the license number and an effective date of closure to lqa@doh.wa.gov.

The owner must notify the department in writing within 30 days of any changes in:

- Name of site, director, or location of site: This information can be updated using the Credential Status Change Form.

- Tests, specialties, and subspecialties; and test methodologies: This information can be updated using the Test Menu Change Form.

License change of ownership license application must be sent to the department 30 days before transfer.

- To change the ownership of a license send in a certificate of waiver MTS/CLIA license application (PDF) and select change of ownership on the first page.

The owner must notify the department in writing within 30 days of any convictions under state or federal law of fraud and abuse, false billing, or kickbacks.

- Send a notice to the lqa@doh.wa.gov with the license number and documentation of convictions.

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- The medical test site must have a written process for reporting SARS-CoV-2 test results.
- Examples of reporting mechanisms that may be used by the laboratories:
  - LIS system/electronic reporting: date, time, and the person that reported the results are indicated in the LIS.
  - Fax machine: date, time, and the person that reported results are indicated on the fax cover sheet or fax "report" sheet.
  - Manual record: date, time, and the person that reported results are indicated in the communication log book.
- All CLIA and medical test site laboratories performing SARS CoV-2 testing must report all (including positive and negative) test results for all testing completed. This includes molecular, antigen and serology testing. This is true even if the IFU references reporting of positive results only.
- The laboratory that performs the SARS-CoV-2 test is responsible for reporting the test result.
- MTS surveyors will assess only if laboratories have, or have not, reported, or attempted to report as described above, SARS-CoV-2 test results. MTS surveyors will not assess if the data elements found in the secretary's June 4, 2020 Guidance were reported or if the timeline in the secretary's guidance was met. In addition, MTS surveyors will not cite data elements or timelines found in the secretary's guidance. See QSO-20-37-CLIA, NH.
- MTS survey staff members may contact resources within the department to verify if a facility is reporting.

Meet the requirements of WAC 246-338-028 On-site Inspections

The department may at any time examine records and conduct an on-site review of the medical test site to determine compliance with chapter 70.42 RCW. This chapter authorizes the department to release all records and information requested by CMS to CMS or CMS agents. The owner must submit to inspections by CMS or CMS agents as a condition of licensure for the purpose of validation or in response to a complaint against the medical test site.

- During the public health emergency, the medical test site program will perform on-site inspections of 5 percent of MTS certificate of waiver (CoW) and provider performed microscopy (PPM) labs performing COVID testing over a three-year period to determine compliance with new rules under notification requirements under WAC

246-338-026(7). Additionally, LQA will confirm that laboratories hold the appropriate type of CLIA certificate (i.e., not testing outside certificate). PPM labs will be assessed for compliance with the applicable MTS requirements for PPM procedures.

The department will use the following process if deficiencies are found during an on-site inspection.

- The department will provide written notice of deficiencies to the medical test site within 10 days of the on-site inspection.
- The department will allow the owner 14 days to write a plan of correction that must detail how and when the medical test site will correct the deficiencies.
- The department will allow the owner 60 days after department approval of the plan of correction to correct a deficiency unless the deficiency is an immediate threat to public health, safety, or welfare.
- The department may impose a directed plan of correction or a partial directed plan of correction as an alternative sanction for any laboratory that has serious deficiencies per 42 C.F.R. 493.1832 and RCW 43.05.100.

Findings of non-compliance during an on-site inspection

- Initial survey – Routine survey (including waived testing) – Complaint investigation
    - On-site or via electronic communication, surveyors will verify that the facility is following the manufacturer's requirements.
        - Deficiency will be cited for not following the manufacturer's test requirements under 246-338-020(1).
    - On-site or via electronic communication, surveyors will verify that a facility has documentation demonstrating compliance with state and federal reporting requirements for SARS-CoV-2 (COVID-19).
        - Deficiency will be cited for failure to report test results under WAC 246-338-026(7).
        - All facilities with a finding on non-compliance with reporting rules will require an on-site or electronic revisit to verify corrections are completed as required.
        - The revisit will include a review that all test results not reported between the date of the initial survey and the date of the revisit. Example: Initial survey is conducted on 3/11/2021. The medical test site reported some, but not all tests run and is cited for not reporting. A revisit is conducted on 7/2/2021. For the revisit on 7/2/2021 the medical test site must have documentation of reporting for those tests missing from the original survey on 3/11/2021 as well as those tests run from 3/11/2021 through 7/2/2021.
        - All revisits are billed to the owner of medical test site, including direct staff time as defined under WAC 246-338-010(17).
    - On-site or via electronic communication, surveyors will determine compliance with the applicable requirements under WAC 246-338 as listed in Table 020-1.

- Repeat (routine, or follow-up) survey – Repeat investigation
    - Collect number of days the facility failed to report test results for SARS-CoV-2. CMP will be $1,000 for repeat violations of 246-338-026(7) and $500 for each subsequent repeat over the past two survey cycles or four years.

How to Report COVID-19 Test Results in Washington State

Please review the Reporting COVID-19 Test Results webpage on how to report test results in Washington State.

Helpful resources for performing testing under a certificate of waiver

- Review the CDC Ready? Set? Test! Booklet for best practices in waived testing,
- Take the Ready? Set? Test! Patient Testing is Important. Get the Right Results online course,

- Complete the CDC Self-Assessment Checklist for Good Testing Practices ,
- MMWR - Good Laboratory Practices for Waived Testing Sites, and
- Review the CDC Guidance for SARS-CoV-2 Point-of-Care and Rapid Testing.